REMARKS

Claims 35-39 are pending in the present application. The Examiner has made the following rejections:

1. Claims 35-39 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to meet the written description requirement.
2. Claims 35-39 are rejected under 35 U.S.C. §101 for allegedly failing to have a credible or well-established utility.
3. Claims 35-39 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled.

These rejections are addressed the order listed above.

1. The Claimed Invention Meets the Requirements of 35 U.S.C. §112, first paragraph.

Claims 35-39 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to meet the written description requirement. (Office Action, page 2). In particular, the Examiner has made a new matter rejection, alleging that the ratio range of 2:20 - 2:50 of amplification vector to first or second expression vector, as recited in Claim 35 and dependent claims, is not supported by the specification. Applicant respectfully disagrees, as the instant specification discloses the recited range of ratios. For example, Section VI, which begins on page 40 at line 11 discusses the co-transfection of cell lines with amplification and expression vectors. At page 41, lines 4-5, Applicant describes co-transfections in which "[t]he ratio of selectable vector, amplification vector and the vector(s) encoding a protein(s) of interest is 1:2:20-50." Thus, Applicant specifically disclosed the ratio 2:20 - 2:50 of amplification vector to first or second expression vector that is recited in the instant claims. Applicant therefore respectfully requests that this rejection be removed.

2. The Claimed Invention Meets the Requirements of 35 U.S.C. §101

Claims 35-39 stand rejected under 35 U.S.C. §101 for allegedly failing to have a credible or well-established utility. (Office Action, page 3) Applicant respectfully asserts that the claimed

invention is supported by patentable utilities.

The Examiner acknowledges that the application is directed toward providing multivalent compositions but asserts that use of the compositions as "vaccines" is not a credible utility. The Examiner's rejection under 35 U.S.C. § 101 is based on his assertion that a method of producing a "vaccine" reads on "a product intended for *prophylactic* treatment of B-cell lymphoma, and also on a product which is intended to be used on members of the population whom are predisposed to acquiring this specific disease. The determination of predisposition is essentially equivalent to a crystal ball into the future" (*emphasis added*).

The Examiner's interpretation of the term "vaccine" as used in the field of the present invention, cancer immunotherapy, is in error. *Therapeutic* cancer vaccines (*i.e.*, for treatment of existing cancers) are known in the art. For example, use of a preparation of a single (monovalent) tumor-derived Ig idiotype protein as a vaccine to treat the patient with the tumor has been described (see, *e.g.*, page 53, lines 17-23 of the specification). Similarly, the compositions produced by the claimed methods are derived from subjects who already have cancer. See, for example, Claim 35, which recites a step of providing malignant cells isolated from a subject having a B-cell lymphoma. Thus, the Examiner's assertions that 1) "vaccines" must have a prophylactic effect, and 2) that the product of the present claims requires determination of predisposition to B-cell lymphoma are incorrect.

Nonetheless, in order to further Applicant's business interests and the prosecution of the present application in a manner consistent with Patent Business Goals, and not in acquiescence to the Examiner's arguments, and while reserving the right to prosecute the original (or similar) claims in the future, Applicant has amended Claims 35-39 to recite production of a " multivalent composition from a subject's B-cell lymphoma cells." These amendments to the claims made herein do not narrow the scope of the claims within the meaning of *Festo*[1] or related cases. Asserted utility of the compositions produced, *e.g.*, for "active idiotype immunotherapy" is found throughout the specification. See, for example, the first sentence of Example 10, on page 88, where it is disclosed that active immunotherapy for B-cell lymphoma involves production of a vaccine comprising the immunoglobulin idiotype corresponding to an antibody on the surface of the B-cell tumor.

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[1] *Festo Corp. v. Shokestu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002)

The Examiner argues that cancer treatments are, in general, unpredictable, and particularly asserts 1) the unreliability of in vitro studies of anticancer drugs (Office Action, page 5); and 2) the unpredictability of antibody treatments of tumors (Office Action, page 6). Neither of these arguments are relevant to the presently claimed invention. In the first instance, the Examiner discusses the screening of unknown chemical compounds in vitro, and the difficulties in extrapolating the data to in vivo protocols. However, the Applicant is not claiming methods of treatment using unknown chemical compounds. Rather, the Applicant is claiming methods of producing multivalent compositions derived from a subject's malignant cells. In the second instance, Weiner is discussing only monoclonal antibody therapy, in which antibodies of the described therapies are used to directly bind to the targeted tumor cells (see, *e.g.*, Weiner abstract at page 41). Such monoclonal antibodies are not related to, nor are they relevant in the analysis of the compositions of the instant claims. In contrast to the monoclonal antibodies discussed by Weiner, the products of the claimed methods are multivalent compositions derived from the tumor cells of a subject for use as *antigens,* to elicit an immune response (*i.e.*, for use in *active* immunotherapy). See, *e.g.*, the discussion of administration of the multivalent compositions ("immunoglobulin-idiotype protein") starting at page 101, line 22, and the discussion of monitoring the treated subject (patient) for immune response *to* the composition (*i.e.*, for production of idiotype-specific antibody) at page 103, lines16-19 of the specification.

For the reasons recited above, Applicant submits that the methods of the instant claims meet the utility requirement of 35 U.S.C. §101, and respectfully requests that this rejection be removed.

3. The Claimed Invention is Enabled.

Claims 35-39 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled. In particular, the Examiner asserts that, in view of the alleged lack of a credible utility, one of skill in the art would not know how to use the claimed invention. Applicant respectfully disagrees. For the reasons recited above, Applicant submits that the methods of the instant claims meet the utility requirement of 35 U.S.C. §101 and have at least the disclosed utility of use as a method of producing a multivalent immunogenic composition derived from a subject's B-cell lymphoma cells. Methods of using the products of the claimed process would be known

to one of skill in the art and, furthermore, are amply described in the specification. See, *e.g.*, the discussion of administration of such compositions from page 101, line 22 to page 103, line 35.

For the reasons recited above, Applicant submits that the methods of the instant claims meet the enablement requirement of 35 U.S.C. §112, and respectfully requests that this rejection be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all reasons for rejection have been addressed and that Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: July 28, 2005

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